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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/839,643

04/20/2001

Gad Keren

34948

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67801

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03/24/2008

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EXAMINER

NGUYEN, CAMTU TRAN

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/839,643	Applicant(s) KEREN ET AL.	
	Examiner Camtu T. Nguyen	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-51 and 59-111 is/are pending in the application.
- 4a) Of the above claim(s) 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-51, 59-61, 63-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-28-2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the embodiment of Figure 2 (devices that are not purely mechanical valves), in the reply filed on 11-15-2007, is acknowledged.

The traversal is on the ground(s) that Figures 3-5 illustrate a method of implanting the device of Figure 1, thus, Figures 3-5 describe a generic process. Such ground(s) of traversal have been carefully considered and thus, the embodiments of Figures 4-5 presented in the previous restriction have been vacated, leaving the previous restriction requirement between Figure 1 & 2 is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-51, 59, 61, 64-68, 70, 71, 73-77, and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (U.S. Patent No. 6,458,153). Bailey et al discloses a shunt apparatus (40) for decreasing pressure comprising a fixation element (42, 44), a shunt tube element (11, 12), and a valve element (28), the valve element (28) selectively permitting blood flow between a first chamber and a second chamber of the heart at a pre-selected pressure differential threshold, at a "positive pressure" that overcomes the bias exerted by the valve

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element (28) to allow from the left atria toward left ventricle (column 8 lines 1-4, column 11 lines 13-27). Flow is selectively permitted when a pressure differential exists between the first & second chambers, thereby would substantially reduce blood pressure in the first chamber. The Bailey et al reference discloses the step of implanting the shunt using a catheter in a percutaneous procedure. The Bailey et al shunt is fully capable of being implanted between any two chambers of the chamber, including between the left & right atria to reduce/decrease blood pressure in the left atria. It would have been obvious to one skilled in the art to use Bailey et al shunt in the method of decrease blood pressure in the heart since the Bailey et al shunt is capable of decreasing blood pressure in any chamber of the heart. With regards to claim 67 reciting the tube, the Bailey et al reference discloses the catheter encompassing the shunt during delivery. With regards to claims 68 & 70 reciting dimensions of the tube, particularly the diameter of the tube is less than 5 mm, it would have been obvious to one skilled in the art to utilize a delivery catheter of less than 5 mm diameter as such would be more effective during insertion as well as during flow conditions.

With regards to claims 59-61 and 73 reciting “adapted”, it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires to ability to so perform. It does not constitute a limitation in a patentable sense. In re Hutchison, 69 USPQ 138.

Claims 59-61, 63-66, 69, 71-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (U.S. Patent No. 4,979,955). Smith discloses in Figures 1-2 a power assisted heart valve (10) benefiting those with diagnosed CHF (congestive heart failure). Figure

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2 illustrates the valve (10) of disc-type disposed between the left ventricle & the aorta for controlling blood flow through the heart via pressure sensors by which closure of the valve is initiated, thereby, decreasing the blood pressure in the ventricle chamber. The Smith heart valve is fully capable of being implanted between any two chambers of the chamber, including between the left & right atria to reduce/decrease blood pressure in the left atria. It would have been obvious to one skilled in the art to use Smith heart valve in the method of decrease blood pressure in the heart since the Smith heart valve is capable of decreasing blood pressure in any chamber of the heart. With regards to the pump, the Smith reference discloses the heart valve system consists of a pacemaker (100) providing pumping functionality for the heart valve (10) and as well as monitoring & control circuits of the pacemaker (100) for purposes of regulating & processing heart valve system. With regards to claim 88 and 99 reciting the pressure in the atrium relative to the opening/closing of the valve, such pressure recitations are within normal pressure range during a diastole phase, therefore deemed non-obvious. With regards to claims 106-108 reciting the opening of the valve upon the pressure sensor reaches a pre-selected pressure, such pre-selected pressure recitations are not out of the ordinary particularly to the pressure in the left atrium in a normal heart with no complications.

With regards to claims 59-61, 63, 72, 73, 80-82, 92, 93, 96, 97, 105, 109 reciting “adapted”, it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires to ability to so perform. It does not constitute a limitation in a patentable sense. In re Hutchison, 69 USPQ 138.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772